

REMARKS

This Amendment responds to the Office Action dated February 18, 2004 in which the Examiner rejected claims 6, 13 and 16 under 35 U.S.C. §112, second paragraph, rejected claims 1, 4, 9 and 12 under 35 U.S.C. §102(b), rejected claims 2-3, 5, 10-11 and 13-17 under 35 U.S.C. §103 and stated that claims 6-8 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. §112 second paragraph.

As indicated above, claims 6, 13 and 16 have been amended in order to more particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Applicant respectfully submits that the amendments to the claims do not narrow the literal scope thereof. Therefore, Applicant respectfully requests the Examiner withdraws the rejection to the claims under 35 U.S.C. §112, second paragraph.

Claims 1 and 3-5 claim a connector comprising a housing and a valve. The valve has a cylindrical base which is tapered such that a wall thickness gradually increases toward a distal end. The valve has a slit having a size such that a tube cannot penetrate through the slit upon opening of the slit. The base of the thick wall section causes a larger deformation at a proximal side than a distal side because of lower flutture strength on the proximal side.

Through the structure of the connector having a cylindrical base which is tapered such that a wall thickness gradually increases toward a distal end and having a size of a slit such that a tube cannot penetrate the slit upon opening of the slit as claimed in claims 1 and 3-5, the claimed invention provides a connector which is free from fluid passage contamination upon engagement with a tube which

enables reliable engagement between the tube and the connector with high sealing capability and which avoids leakage from the connector during and after engagement/disengagement of the tube with the connector. The prior art does not show, teach or suggest the invention as claimed in claims 1 and 3-5.

As indicated above, claims 1 and 3-5, 11 and 14 have been amended to make explicit what is implicit in the claims. The amendments are unrelated to a statutory requirement for patentability and do not narrow the literal scope of the claims.

Claims 1, 4, 9 and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by *Atkinson et al.* (U.S. Patent No. 5,533,708).

Atkinson et al. appears to disclose a coupling site which includes a valve element and support structure for cooperation with a standard male luer lock having a male luer taper and a threaded locking collar. (col. 1, lines 17-20) As seen in FIGS. 2 and 4, the support base 12 preferably includes a tubular luer taper portion 18 defining a longitudinal axis 20 of the coupling site 10. The luer taper portion 18 is surrounded by a threaded locking collar 22 such that the coupling site 10 may be attached to a standard female luer fitting. In addition, an outwardly extending flange portion 24 is attached to an inner end of the luer taper portion 18 extending from an end wall 26 of the collar 22. The valve member 16 includes a tubular body portion 28 extending substantially parallel to the longitudinal axis 20 and defining a first end 30 and a second end 32 wherein the second end 32 is in contact with the support base 12 adjacent to the end wall 26. The valve element 16 further includes a thin flexible diaphragm 34 extending across the first end 30 of the body portion 16. The diaphragm 34 includes means defining a slit 36 extending diametrically across the diaphragm 34. In addition, the diaphragm 34 defines opposing first and second sides

38, 40 wherein the first side 38 is formed as a concave surface and the second side 40 is formed as a convex surface. The concave first surface 38 includes a peripheral edge lying in a plane defined by an annular end surface 42 of the body portion 16. It should be noted that the first surface 38 is provided with a relatively shallow curvature such that the first surface 38 is easily cleaned by wiping of the surface. Also, as a result of forming the diaphragm 34 curved inwardly toward the port base 12, fluid pressure within the site 10 will exert an outwardly directed force on the diaphragm 34 and will tend to cause the material surrounding the slit 36 to compress inwardly, thus biasing the slit closed. (col. 6, line 44 through col. 7, line 8) With reference to FIG. 3, it should also be noted that the male luer taper 50 causes the diaphragm 34 to be stretched and pushed into a distorted position adjacent to the inner wall 48, with an accompanying distortion of the ribs 44, 46. Further, the coupling site 10 of the present invention incorporates a flexible diaphragm member 34 having a slit 36 wherein the slit is biased to a closed position through forces exerted on the diaphragm member by a supporting tubular body portion 28 forming a passage for receiving the male luer taper. Providing such a diaphragm member 34 for forming the seal on the site end results in a highly resilient opening offering reduced resistance to forces pushing the male luer taper 50 or other cannula into the coupling site 10 while also providing a reliable closure element when the male luer taper 50 is removed from the site 10. (col. 8, line 61 through col. 9, line 9) The embodiment of FIGS. 6-8 differs from the previous embodiment in that the area surrounded by the flange portion 24' includes an enlarged passage defining a luer slip 66' which is adapted to receive the end of a standard male luer taper 50'. The area of the second end 32' of the body portion 16' and the second end 56' of the

retainer 14' are formed with an enlarged diameter, as compared to the previous embodiment, in order to accommodate the enlarged luer slip area 66'. (col. 9, lines 19-27)

Thus, *Atkinson et al.* merely discloses, as shown in Fig. 3, a male luer taper 50 which is inserted through a slit 36 in diaphragm 34. Nothing in *Atkinson et al.* shows, teaches or suggests a slit has a size such that a tube cannot penetrate through the slit upon opening of the slit as claimed in claims 1 and 4. Rather, *Atkinson et al.* teaches away from the claimed invention and allows the taper 50 to penetrate through the slit 36 of the diaphragm.

Additionally, *Atkinson et al.* merely discloses a diaphragm having a tubular body portion 28. Nothing in *Atkinson et al.* shows, teaches or suggests a valve having a cylindrical base which is tapered such that a wall thickness gradually increases toward a distal end as claimed in claims 1 and 4. Rather, *Atkinson et al.* teaches away from the claimed invention and merely discloses a tubular body portion 28.

Since nothing in *Atkinson et al.* shows, teaches or suggests a) a slit of a valve having a size such that a tube cannot penetrate the slit upon opening of the slit and b) a cylindrical base which is tapered such that a wall thickness gradually increases toward a distal end as claimed in claims 1 and 4, Applicant respectfully requests the Examiner withdraws the rejection to claims 1 and 4 under 35 U.S.C. §102(b).

Claims 9 and 12 depend from claim 1 and recite additional features. Applicant respectfully submits that claims 9 and 12 would not have been anticipated by *Atkinson et al.* within the meaning of 35 U.S.C. §102(b) at least for the reasons as

set forth above. Therefore, Applicant respectfully requests the Examiner withdraws the rejection to claims 9 and 12 under 35 U.S.C. §102(b).

Claims 2-3, 5, 10-11 and 13 were rejected under 35 U.S.C. §103 as being unpatentable over *Atkinson et al.* in view of *Orr et al.* (U.S. Patent No. 6,050,978).

As discussed above, nothing in *Atkinson et al.* shows, teaches or suggests a) a slit has a size such that a tube cannot penetrate through a slit upon opening of the slit and b) a valve having a cylindrical base which is tapered such that a wall thickness gradually increases toward a distal end as claimed in claims 3 and 5.

Orr et al. appears to disclose the field of needleless valve connectors that may be used with medical devices such as catheters, especially intravascular (IV) catheters, IV administration sets, syringes and medicine vials. (col. 1, lines 5-9) The needleless valve connector 10 comprises three main pieces, an upper body portion 20, a lower body portion 30 and a movable diaphragm assembly 40. The proximal end of upper body portion 20 defines a neck portion 21 having an inlet opening 22 therein with a female luer configuration. Upper body portion 20 flares outwardly from neck portion 21 to a skirt portion 23 with a shoulder 24 therebetween. Skirt 23 extends from shoulder 24 to the distal end of upper body portion 20 and preferably has a rectangular cross-section. The distal end of the lower body portion 30 defines an outlet opening 31 having a male luer configuration. Integrally formed and in fluid communication with outlet opening 31 is an internal cannula 32. A base plate 33 extends from the distal end of internal cannula 32 to the outer wall 34 of lower body portion 30. Outer wall 34 engages skirt 23 to define the cavity 50 of needleless valve connector 10. (col. 4, lines 30-47) Movable diaphragm assembly 40 preferably includes a diaphragm 41, a plurality of flexible legs 42 integrally formed with

diaphragm 41 and an annular flange 43 integrally formed with flexible legs 42 at the distal end thereof. These flexible legs 42 provide the biasing force to urge diaphragm 41 toward inlet opening 22. Although flexible legs 42 are preferably integrally formed with diaphragm 41, a separate biasing mechanism, such as a standard spring, could be used and bonded by any standard mechanism to diaphragm 41. Diaphragm 41 defines a slit 44 therein. Diaphragm 41 is oversized in relation to inlet opening 22 to ensure that slit 44 remains closed when needleless valve connector 10 is closed. Diaphragm 41 can simply have a circular cross-section with a diameter larger than the diameter of inlet opening 22. (col. 5, lines 16-30) When movable diaphragm assembly 40 is properly aligned with internal cannula 32 and diaphragm 41 is moved distally, e.g. by the male luer end of a syringe, each cam 46 engages a proximal portion of internal cannula 32 between slots 36 during downward movement of diaphragm 41. Further downward movement of diaphragm 41 causes each cam 46 to compress the proximal end of internal cannula 32. See FIGS. 4, 7 and 13. This compression results in the proximal portion of internal cannula 32 having an inclined leading edge, i.e. a tapered surface, and also results in the proximal end of internal cannula 32 having a smaller diameter. This configuration facilitates movement of the proximal portion of internal cannula 32 through slit 44 of diaphragm 41. Once diaphragm 41 has been moved to a position distal of slots 36 of internal cannula 32, the proximal portion of internal cannula 32 is no longer constrained by diaphragm 41. Thus, the proximal portion of internal cannula 32 can return to its original unbiased position and provides an inlet opening to lumen 35 having a diameter substantially equal to the diameter of lumen 35. See

FIGS. 5 and 8. Thus, fluid can freely flow through the bore of internal cannula 32.

(col. 6, lines 1-21)

Thus, *Orr et al.* merely discloses a movable diaphragm assembly 40 including a diaphragm 41 and a plurality of flexible legs 42 and an annular flange 43 integrally formed with a flexible legs 42. Nothing in *Orr et al.* shows, teaches or suggests a valve having a cylindrical base which is tapered such that a wall thickness gradually increases toward a distal end as claimed in claims 3 and 5. Rather, *Orr et al.* teaches away from the claimed invention and merely discloses a diaphragm 41, flexible legs 42 and annular 43.

The combination of *Atkinson et al.* and *Orr et al.* would not be possible since *Atkinson et al.* teaches that a taper 50 passes through the valve element 16 whereas *Orr et al.* uses a cannular 32 which is an essential requirement for the connection of the two tubes and one in which the tubes do not pass through the valve 41 to be connected to each other. Thus, Applicant respectfully submits that since two completely different techniques are used, a person of ordinary skill in the art would have no motivation to combine these two techniques. Furthermore, even assuming arguendo that the references could be combined, nothing in the combination of the references shows, teaches or suggests a valve having a cylindrical base which is tapered such that a wall thickness gradually increases toward a distal end. Therefore, Applicant respectfully requests the Examiner withdraws the rejection to claims 3 and 5 under 35 U.S.C. §103.

Claims 2, 11 and 13 depend from claims 1 and recite additional features. Applicants respectfully submit that claims 2, 11 and 13 would not have been obvious within the meaning of 35 U.S.C. §103 over *Atkinson et al.* and *Orr et al.* at least for

the reasons as set forth above. Therefore, Applicant respectfully requests the Examiner withdraws the rejection to claims 2, 11 and 13 under 35 U.S.C. §103.

Claims 14-17 were rejected under 35 U.S.C. §103 as being unpatentable over *Atkinson et al.* and *Orr et al.* and further in view of *Jepson et al.* (WO 90/11103).

Applicant respectfully traverses the Examiner's rejection of the claims under 35 U.S.C. §103. The claims have been reviewed in light of the Office Action, and for reasons which will be set forth below, Applicant respectfully requests the Examiner withdraws the rejection to the claims and allows the claims to issue.

As discussed above, since nothing in *Atkinson et al.* and *Orr et al.* show, teach or suggest the primary features as claimed in claim 1, Applicant respectfully submits that the combination of the primary references with the secondary references to *Jepson et al.* will not overcome the deficiencies of the primary references. Therefore, Applicant respectfully requests the Examiner withdraws the rejection to claims 14-17 under 35 U.S.C. §103.

The prior art of record, which is not relied upon, is acknowledged. The references taken singularly or in combination do not anticipate or make obvious the claimed invention.

Thus, it now appears that the application is in condition for reconsideration and allowance. Reconsideration and allowance at an early date are respectfully requested.

If for any reason the Examiner feels that the application is not now in condition for allowance, the Examiner is requested to contact, by telephone, the Applicant's undersigned attorney at the indicated telephone number to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed within the current set shortened statutory period, Applicant respectfully petitions for an appropriate extension of time. The fees for such extension of time may be charged to our Deposit Account No. 02-4800.

In the event that any additional fees are due with this paper, please charge our Deposit Account No. 02-4800.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 

Ellen Marcie Emas
Registration No. 32,131

Date: May 18, 2004

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620